105TH CONGRESS 1ST SESSION

S. 311

To amend title XVIII of the Social Security Act to improve preventive benefits under the Medicare program.

IN THE SENATE OF THE UNITED STATES

February 12, 1997

Mr. Graham introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend title XVIII of the Social Security Act to improve preventive benefits under the Medicare program.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.
- 4 (a) Short Title.—This Act may be cited as the
- 5 "Medicare Preventive Benefit Improvement Act of 1997".
- 6 (b) Table of Contents.—The table of contents of
- 7 this Act is as follows:
 - Sec. 1. Short title; table of contents.
 - Sec. 2. Screening mammography.
 - Sec. 3. Screening pap smear and pelvic exams.
 - Sec. 4. Coverage of colorectal screening.
 - Sec. 5. Prostate cancer screening tests.
 - Sec. 6. Diabetes screening benefits.
 - Sec. 7. Effective date.

1 SEC. 2. SCREENING MAMMOGRAPHY.

- 2 (a) Providing Annual Screening Mammography
- 3 FOR WOMEN OVER AGE 49.—Section 1834(c)(2)(A) of
- 4 the Social Security Act (42 U.S.C. 1395m(c)(2)(A)) is
- 5 amended—
- 6 (1) in clause (iv), by striking "but under 65
- 7 years of age,", and
- 8 (2) by striking clause (v).
- 9 (b) Waiver of Deductible.—The first sentence of
- 10 section 1833(b) of the Social Security Act (42 U.S.C.
- 11 1395l(b)) is amended—
- 12 (1) by striking "and" before "(4)", and
- 13 (2) by inserting before the period at the end the
- following: ", and (5) such deductible shall not apply
- 15 with respect to screening mammography (as de-
- scribed in section 1861(jj))".
- 17 (c) Conforming Amendment.—Section
- 18 1834(c)(1)(C) of the Social Security Act (42 U.S.C.
- 19 1395m(c)(1)(C)) is amended by striking ", subject to the
- 20 deductible established under section 1833(b),".
- 21 SEC. 3. SCREENING PAP SMEAR AND PELVIC EXAMS.
- 22 (a) Coverage of Pelvic Exam; Increasing Fre-
- 23 QUENCY OF COVERAGE OF PAP SMEAR.—Section
- 24 1861(nn) of the Social Security Act (42 U.S.C.
- 25 1395x(nn)) is amended—

| 1 | (1) in the heading, by striking "Smear" and in- |
|----|--|
| 2 | serting "Smear; Screening Pelvic Exam"; |
| 3 | (2) by striking "(nn)" and inserting "(nn)(1)"; |
| 4 | (3) by striking "3 years" and all that follows |
| 5 | and inserting "3 years, or during the preceding year |
| 6 | in the case of a woman described in paragraph (3)."; |
| 7 | and |
| 8 | (4) by adding at the end the following: |
| 9 | "(2) The term 'screening pelvic exam' means a pelvic |
| 10 | examination provided to a woman if the woman involved |
| 11 | has not had such an examination during the preceding 3 |
| 12 | years, or during the preceding year in the case of a woman |
| 13 | described in paragraph (3), and includes a clinical breast |
| 14 | examination. |
| 15 | "(3) A woman described in this paragraph is a |
| 16 | woman who— |
| 17 | "(A) is of childbearing age and has not had a |
| 18 | test described in this subsection during each of the |
| 19 | preceding 3 years that did not indicate the presence |
| 20 | of cervical cancer; or |
| 21 | "(B) is at high risk of developing cervical can- |
| 22 | cer (as determined pursuant to factors identified by |
| 23 | the Secretary).". |

| 1 | (b) WAIVER OF DEDUCTIBLE.—The first sentence of |
|----|---|
| 2 | section 1833(b) of the Social Security Act (42 U.S.C. |
| 3 | 1395l(b)), as amended by section 2(b), is amended— |
| 4 | (1) by striking "and" before "(5)", and |
| 5 | (2) by inserting before the period at the end the |
| 6 | following: ", and (6) such deductible shall not apply |
| 7 | with respect to screening pap smear and screening |
| 8 | pelvic exam (as described in section 1861(nn))". |
| 9 | (c) Conforming Amendments.—Sections |
| 10 | 1861(s)(14) and 1862(a)(1)(F) of the Social Security Act |
| 11 | $(42 \ U.S.C. \ 1395x(s)(14), \ 1395y(a)(1)(F))$ are each |
| 12 | amended by inserting "and screening pelvic exam" after |
| 13 | "screening pap smear". |
| 14 | SEC. 4. COVERAGE OF COLORECTAL SCREENING. |
| 15 | (a) Coverage.— |
| 16 | (1) In general.—Section 1861 of the Social |
| 17 | Security Act (42 U.S.C. 1395x) is amended— |
| 18 | (A) in subsection (s)(2)— |
| 19 | (i) by striking "and" at the end of |
| 20 | subparagraphs (N) and (O), and |
| 21 | (ii) by inserting after subparagraph |
| 22 | (O) the following: |
| 23 | "(P) colorectal cancer screening tests (as de- |
| 24 | fined in subsection (oo)); and"; and |
| | |

| 1 | "Colorectal Cancer Screening Tests |
|----|---|
| 2 | "(oo)(1) The term 'colorectal cancer screening test' |
| 3 | means, unless determined otherwise pursuant to section |
| 4 | 4(a)(2) of Medicare Preventive Benefit Improvement Act |
| 5 | of 1997, any of the following procedures furnished to an |
| 6 | individual for the purpose of early detection of colorectal |
| 7 | cancer: |
| 8 | "(A) Screening fecal-occult blood test. |
| 9 | "(B) Screening flexible sigmoidoscopy. |
| 10 | "(C) Screening barium enema. |
| 11 | "(D) In the case of an individual at high risk |
| 12 | for colorectal cancer, screening colonoscopy or |
| 13 | screening barium enema. |
| 14 | "(E) For years beginning after 2002, such |
| 15 | other procedures as the Secretary finds appropriate |
| 16 | for the purpose of early detection of colorectal can- |
| 17 | cer, taking into account changes in technology and |
| 18 | standards of medical practice, availability, effective- |
| 19 | ness, costs, the particular screening needs of racial |
| 20 | and ethnic minorities in the United States and such |
| 21 | other factors as the Secretary considers appropriate. |

| 1 | "(2) In paragraph (1)(D), an 'individual at high risk |
|----|---|
| 2 | for colorectal cancer' is an individual who, because of fam- |
| 3 | ily history, prior experience of cancer or precursor neo- |
| 4 | plastic polyps, a history of chronic digestive disease condi- |
| 5 | tion (including inflammatory bowel disease, Crohn's Dis- |
| 6 | ease, or ulcerative colitis), the presence of any appropriate |
| 7 | recognized gene markers for colorectal cancer, or other |
| 8 | predisposing factors, faces a high risk for colorectal can- |
| 9 | cer.". |
| 10 | (2) Review of coverage of colorectal |
| 11 | CANCER SCREENING TESTS.— |
| 12 | (A) IN GENERAL.—Not later than 2 years |
| 13 | after the date of enactment of this Act (and pe- |
| 14 | riodically thereafter), the Secretary of Health |
| 15 | and Human Services (in this paragraph re- |
| 16 | ferred to as the "Secretary") shall review— |
| 17 | (i) the standards of medical practice |
| 18 | with regard to colorectal cancer screening |
| 19 | tests (as defined in section 1861(oo) of the |
| 20 | Social Security Act (42 U.S.C. 1395x(oo))) |
| 21 | (as added by paragraph (1) of this sec- |
| 22 | tion); |
| 23 | (ii) the availability, effectiveness, |
| 24 | costs, and cost-effectiveness of colorectal |
| 25 | cancer screening tests covered under title |

| 1 | XVIII of the Social Security Act (42 |
|----|--|
| 2 | U.S.C. 1395 et seq.) at the time of such |
| 3 | review; |
| 4 | (iii) the particular screening needs of |
| 5 | racial and ethnic minorities in the United |
| 6 | States; and |
| 7 | (iv) such other factors as the Sec- |
| 8 | retary considers appropriate with regard to |
| 9 | the coverage of colorectal cancer screening |
| 10 | tests under the Medicare program. |
| 11 | (B) Determination.—If the Secretary |
| 12 | determines it appropriate based on the review |
| 13 | conducted pursuant to subparagraph (A), the |
| 14 | Secretary shall issue and publish a determina- |
| 15 | tion that one or more colorectal cancer screen- |
| 16 | ing tests described in section 1861(00) of the |
| 17 | Social Security Act (42 U.S.C. 1395x(oo)) (as |
| 18 | added by paragraph (1) of this section) shall no |
| 19 | longer be covered under that section. |
| 20 | (b) Frequency and Payment Limits.— |
| 21 | (1) In general.—Section 1834 of the Social |
| 22 | Security Act (42 U.S.C. 1395m) is amended by in- |
| 23 | serting after subsection (c) the following: |
| 24 | "(d) Frequency and Payment Limits for |
| 25 | COLORECTAL CANCER SCREENING TESTS — |

| 1 | "(1) Screening fecal-occult blood |
|----|--|
| 2 | TESTS.— |
| 3 | "(A) PAYMENT LIMIT.—In establishing fee |
| 4 | schedules under section 1833(h) with respect to |
| 5 | colorectal cancer screening tests consisting of |
| 6 | screening fecal-occult blood tests, except as pro- |
| 7 | vided by the Secretary under paragraph (5)(A), |
| 8 | the payment amount established for tests per- |
| 9 | formed— |
| 10 | "(i) in 1998 shall not exceed \$5; and |
| 11 | "(ii) in a subsequent year, shall not |
| 12 | exceed the limit on the payment amount |
| 13 | established under this subsection for such |
| 14 | tests for the preceding year, adjusted by |
| 15 | the applicable adjustment under section |
| 16 | 1833(h) for tests performed in such year. |
| 17 | "(B) Frequency Limit.—Subject to revi- |
| 18 | sion by the Secretary under paragraph (5)(B), |
| 19 | no payment may be made under this part for |
| 20 | colorectal cancer screening test consisting of a |
| 21 | screening fecal-occult blood test— |
| 22 | "(i) if the individual is under 50 years |
| 23 | of age; or |

| 1 | "(ii) if the test is performed within |
|----|--|
| 2 | the 11 months after a previous screening |
| 3 | fecal-occult blood test. |
| 4 | "(2) Screening for individuals not at |
| 5 | HIGH RISK.—Subject to revision by the Secretary |
| 6 | under paragraph (5)(B), no payment may be made |
| 7 | under this part for a colorectal cancer screening test |
| 8 | consisting of a screening flexible sigmoidoscopy or |
| 9 | screening barium enema— |
| 10 | "(i) if the individual is under 50 years |
| 11 | of age; or |
| 12 | "(ii) if the procedure is performed |
| 13 | within the 47 months after a previous |
| 14 | screening flexible sigmoidoscopy or screen- |
| 15 | ing barium enema. |
| 16 | "(3) Screening for individuals at high |
| 17 | RISK FOR COLORECTAL CANCER.—Subject to revi- |
| 18 | sion by the Secretary under paragraph (5)(B), no |
| 19 | payment may be made under this part for a |
| 20 | colorectal cancer screening test consisting of a |
| 21 | screening colonoscopy or screening barium enema for |
| 22 | individuals at high risk for colorectal cancer if the |
| 23 | procedure is performed within the 23 months after |
| 24 | a previous screening colonoscopy or screening bar- |

ium enema.

25

"(4) Payment amounts for certain colorectal cancer screening tests.—The Section 1848 with respect each colorectal cancer screening tests described in subparagraphs (B), (C), and (D) of section 1861(oo)(1) that are consistent with payment amounts under such section for similar or related services, except that such payment amount shall be established without regard to section 1848(a)(2)(A).

"(5) REDUCTIONS IN PAYMENT LIMIT AND RE-VISION OF FREQUENCY.—

"(A) REDUCTIONS IN PAYMENT LIMIT FOR SCREENING FECAL-OCCULT BLOOD TESTS.—
The Secretary shall review from time to time the appropriateness of the amount of the payment limit established for screening fecal-occult blood tests under paragraph (1)(A). The Secretary may, with respect to tests performed in a year after 2000, reduce the amount of such limit as it applies nationally or in any area to the amount that the Secretary estimates is required to assure that such tests of an appropriate quality are readily and conveniently available during the year.

| 1 | "(B) REVISION OF FREQUENCY.— |
|----|--|
| 2 | "(i) Review.—The Secretary shall re- |
| 3 | view periodically the appropriate frequency |
| 4 | for performing colorectal cancer screening |
| 5 | tests based on age and such other factors |
| 6 | as the Secretary believes to be pertinent. |
| 7 | "(ii) REVISION OF FREQUENCY.—The |
| 8 | Secretary, taking into consideration the re- |
| 9 | view made under clause (i), may revise |
| 10 | from time to time the frequency with |
| 11 | which such tests may be paid for under |
| 12 | this subsection, but no such revision shall |
| 13 | apply to tests performed before January 1, |
| 14 | 2001. |
| 15 | "(6) Limiting charges of nonparticipating |
| 16 | PHYSICIANS.— |
| 17 | "(A) IN GENERAL.—In the case of a |
| 18 | colorectal cancer screening test consisting of a |
| 19 | screening flexible sigmoidoscopy or screening |
| 20 | barium enema, or a screening colonoscopy or |
| 21 | screening barium enema provided to an individ- |
| 22 | ual at high risk for colorectal cancer for which |
| 23 | payment may be made under this part, if a |
| 24 | nonparticipating physician provides the proce- |
| 25 | dure to an individual enrolled under this part, |

the physician may not charge the individual more than the limiting charge (as defined in section 1848(g)(2)).

"(B) Enforcement.—If a physician or supplier knowingly and willfully imposes a charge in violation of subparagraph (A), the Secretary may apply sanctions against such physician or supplier in accordance with section 1842(j)(2).".

(c) Conforming Amendments.—

- (1) Paragraphs (1)(D) and (2)(D) of section 1833(a) of the Social Security Act (42 U.S.C. 1395l(a)) are each amended by inserting "or section 1834(d)(1)" after "subsection (h)(1)".
- (2) Section 1833(h)(1)(A) of the Social Security Act (42 U.S.C. 1395l(h)(1)(A)) is amended by striking "The Secretary" and inserting "Subject to paragraphs (1) and (5)(A) of section 1834(d), the Secretary".
- (3) Clauses (i) and (ii) of section 1848(a)(2)(A) of the Social Security Act (42 U.S.C. 1395w–4(a)(2)(A)) are each amended by inserting after "a service" the following: "(other than a colorectal cancer screening test consisting of a screening colonoscopy or screening barium enema provided to

| 1 | an individual at high risk for colorectal cancer or a |
|----|---|
| 2 | screening flexible sigmoidoscopy or screening barium |
| 3 | enema)''. |
| 4 | (4) Section 1862(a) of the Social Security Act |
| 5 | (42 U.S.C. 1395y(a)) is amended— |
| 6 | (A) in paragraph (1)— |
| 7 | (i) in subparagraph (E), by striking |
| 8 | "and" at the end, |
| 9 | (ii) in subparagraph (F), by striking |
| 10 | the semicolon at the end and inserting ", |
| 11 | and", and |
| 12 | (iii) by adding at the end the follow- |
| 13 | ing: |
| 14 | "(G) in the case of colorectal cancer screening |
| 15 | tests, which are performed more frequently than is |
| 16 | covered under section 1834(d);"; and |
| 17 | (B) in paragraph (7), by striking "para- |
| 18 | graph $(1)(B)$ or under paragraph $(1)(F)$ " and |
| 19 | inserting "subparagraph (B), (F), or (G) of |
| 20 | paragraph (1)". |
| 21 | SEC. 5. PROSTATE CANCER SCREENING TESTS. |
| 22 | (a) Coverage.—Section 1861 of the Social Security |
| 23 | Act (42 U.S.C. 1395x), as amended by section 4(a), is |
| 24 | amended— |
| 25 | (1) in subsection $(s)(2)$ — |

| 1 | (A) by striking "and" at the end of sub- |
|----|--|
| 2 | paragraph (P); |
| 3 | (B) by adding "and" at the end of sub- |
| 4 | paragraph (Q); and |
| 5 | (C) by adding at the end the following: |
| 6 | "(R) prostate cancer screening tests (as defined |
| 7 | in subsection (pp)); and"; and |
| 8 | (2) by adding at the end the following: |
| 9 | "Prostate Cancer Screening Tests |
| 10 | "(pp)(1) The term 'prostate cancer screening test' |
| 11 | means a test that consists of any (or all) of the procedures |
| 12 | described in paragraph (2) provided for the purpose of |
| 13 | early detection of prostate cancer to a man over 50 years |
| 14 | of age who has not had such a test during the preceding |
| 15 | year. |
| 16 | "(2) The procedures described in this paragraph are |
| 17 | as follows: |
| 18 | "(A) A digital rectal examination. |
| 19 | "(B) A prostate-specific antigen blood test. |
| 20 | "(C) For years beginning after 2001, such |
| 21 | other procedures as the Secretary finds appropriate |
| 22 | for the purpose of early detection of prostate cancer, |
| 23 | taking into account changes in technology and |

| 1 | standards of medical practice, availability, effective- |
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| 2 | ness, costs, and such other factors as the Secretary |
| 3 | considers appropriate.". |
| 4 | (b) Payment for Prostate-specific Antigen |
| 5 | BLOOD TEST UNDER CLINICAL DIAGNOSTIC LABORA- |
| 6 | TORY TEST FEE SCHEDULES.—Section 1833(h)(1)(A) of |
| 7 | the Social Security Act (42 U.S.C. 1395l(h)(1)(A)) is |
| 8 | amended by inserting after "laboratory tests" the follow- |
| 9 | ing: "(including prostate cancer screening tests under sec- |
| 10 | tion 1861(pp) consisting of prostate-specific antigen blood |
| 11 | tests)". |
| 12 | (c) Conforming Amendment.—Section 1862(a) of |
| 13 | the Social Security Act (42 U.S.C. 1395y(a)), as amended |
| 14 | by section 4(c)(4), is amended— |
| 15 | (1) in paragraph (1)— |
| 16 | (A) in subparagraph (F), by striking |
| 17 | "and" at the end, |
| 18 | (B) in subparagraph (G), by striking the |
| 19 | semicolon at the end and inserting ", and", and |
| 20 | (C) by adding at the end the following: |
| 21 | "(H) in the case of prostate cancer screening |
| 22 | tests (as defined in section 1861(oo)), which are per- |
| 23 | formed more frequently than is covered under such |
| 24 | section;"; and |

| 1 | (2) in paragraph (7), by striking "or (G)" and |
|----|--|
| 2 | inserting "(G), or (H)". |
| 3 | SEC. 6. DIABETES SCREENING BENEFITS. |
| 4 | (a) Coverage of Diabetes Outpatient Self- |
| 5 | MANAGEMENT TRAINING SERVICES.— |
| 6 | (1) In General.—Section 1861 of the Social |
| 7 | Security Act (42 U.S.C. 1395x), as amended by sec- |
| 8 | tions 4(a) and 5(a), is amended— |
| 9 | (A) in subsection (s)(2)— |
| 10 | (i) by striking "and" at the end of |
| 11 | subparagraph (Q); |
| 12 | (ii) by adding "and" at the end of |
| 13 | subparagraph (R); and |
| 14 | (iii) by adding at the end the follow- |
| 15 | ing: |
| 16 | "(S) diabetes outpatient self-management train- |
| 17 | ing services (as defined in subsection (qq)); and"; |
| 18 | and |
| 19 | (B) by adding at the end the following: |
| 20 | "Diabetes Outpatient Self-Management Training Services |
| 21 | "(qq)(1) The term 'diabetes outpatient self-manage- |
| 22 | ment training services' means educational and training |
| 23 | services furnished to an individual with diabetes by or |
| 24 | under arrangements with a certified provider (as described |

- 1 in paragraph (2)(A)) in an outpatient setting by an indi-
- 2 vidual or entity who meets the quality standards described
- 3 in paragraph (2)(B), but only if the physician who is man-
- 4 aging the individual's diabetic condition certifies that such
- 5 services are needed under a comprehensive plan of care
- 6 related to the individual's diabetic condition to provide the
- 7 individual with necessary skills and knowledge (including
- 8 skills related to the self-administration of injectable drugs)
- 9 to participate in the management of the individual's condi-
- 10 tion.
- 11 "(2) In paragraph (1)—
- 12 "(A) a 'certified provider' is an individual or
- entity that, in addition to providing diabetes out-
- patient self-management training services, provides
- other items or services for which payment may be
- made under this title; and
- 17 "(B) an individual or entity meets the quality
- standards described in this paragraph if the individ-
- 19 ual or entity meets quality standards established by
- the Secretary, except that the individual or entity
- shall be deemed to have met such standards if the
- individual or entity meets applicable standards origi-
- 23 nally established by the National Diabetes Advisory
- 24 Board and subsequently revised by organizations
- who participated in the establishment of standards

- by such Board, or is recognized by the American Diabetes Association as meeting standards for furnishing the services.".
- (2) Consultation with organizations in 5 ESTABLISHING PAYMENT AMOUNTS FOR SERVICES 6 PROVIDED BY PHYSICIANS.—In establishing payment 7 amounts under section 1848(a) of the Social Secu-8 rity Act (42 U.S.C. 1395w-4(a)) for physicians' 9 services consisting of diabetes outpatient self-man-10 agement training services, the Secretary of Health 11 and Human Services shall consult with appropriate 12 organizations, including the American Diabetes As-13 sociation, in determining the relative value for such 14 services under section 1848(c)(2) of such Act.
- 15 (b) Blood-testing Strips for Individuals With16 Diabetes.—
- 17 (1) Including strips as durable medical 18 EQUIPMENT.—The first sentence of section 1861(n) 19 of the Social Security Act (42 U.S.C. 1395x(n)) is 20 amended by inserting before the semicolon the fol-21 lowing: ", and includes blood-testing strips for indi-22 viduals with diabetes without regard to whether the 23 individual has Type I or Type II diabetes or to the individual's use of insulin (as determined under 24

| 1 | standards established by the Secretary in consulta- |
|----|---|
| 2 | tion with the American Diabetes Association)". |
| 3 | (2) Payment for strips based on meth- |
| 4 | ODOLOGY FOR INEXPENSIVE AND ROUTINELY PUR- |
| 5 | CHASED EQUIPMENT.—Section 1834(a)(2)(A) of the |
| 6 | Social Security Act (42 U.S.C. 1395m(a)(2)(A)) is |
| 7 | amended— |
| 8 | (A) by striking "or" at the end of clause |
| 9 | (ii); |
| 10 | (B) by adding "or" at the end of clause |
| 11 | (iii); and |
| 12 | (C) by inserting after clause (iii) the fol- |
| 13 | lowing: |
| 14 | "(iv) which is a blood-testing strip for |
| 15 | an individual with diabetes,". |
| 16 | (c) Establishment of Outcome Measures for |
| 17 | Beneficiaries With Diabetes.— |
| 18 | (1) IN GENERAL.—The Secretary of Health and |
| 19 | Human Services, in consultation with appropriate |
| 20 | organizations (including the American Diabetes As- |
| 21 | sociation), shall establish outcome measures, includ- |
| 22 | ing glysolated hemoglobin (past 90-day average |
| 23 | blood sugar levels), for purposes of evaluating the |
| 24 | improvement of the health status of Medicare bene- |
| 25 | ficiaries with diabetes mellitus |

1 (2) RECOMMENDATIONS FOR MODIFICATIONS 2 TO SCREENING BENEFITS.—Taking into account in-3 formation on the health status of Medicare beneficiaries with diabetes mellitus as measured under 5 the outcome measures established under subparagraph (A), the Secretary shall from time to time 6 7 submit recommendations to Congress regarding modifications to the coverage of services for such 8 9 beneficiaries under the Medicare program.

10 SEC. 7. EFFECTIVE DATE.

The amendments made by this Act shall apply to 12 items and services furnished on or after January 1, 1998.

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